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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,807	10/01/2001	Reuben Matalon	SHUTT-I C1	3645

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EXAMINER

MAYER, SUZANNE MARIE

ART UNIT PAPER NUMBER

1653

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/965,807	Applicant(s) MATALON ET AL.	
	Examiner Suzanne M. Mayer, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22,24,66-75 and 80-91 is/are pending in the application.
 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 67,81 and 82 is/are allowed.
- 6) ☒ Claim(s) 20,22,24,66-75,80 and 83-91 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on December 02, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

EXAMINERS RESPONSE

The instant Office action is in response to the Amendments and Remarks filed December 2 and 7, 2004.

Information Disclosure Statement

1. The response to the office action filed December 2, 2004 stated that the missing references would be provided but have not yet been received by the office. Thus this objection is maintained.

Drawings

2. The drawings were received on December 12, 2004. These drawings are accepted by the examiner.

Claim Objections

2. The examiners acknowledges Applicants response and hereby withdraws the claim objections from the original Office action of July 2, 2004.

Claim Rejections

35 USC § 112, 2nd paragraph

3. The rejection of Claims 22, 67-75 and 81-82 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn for claims 22, 68-

75 and 81-82. The rejection is maintained for claim 67 for the recitation of 'normal-type', however, it is noted that this appears to be a typographical error.

4. The rejection for the Claims 22, 24 and 66 from the previous Office action because of the recitation of the phrase 'allelic variant' is maintained. Applicant's arguments filed Dec. 2, 2004 have been fully considered but they are not persuasive because despite the addition of the recitation that it is naturally occurring, the ambiguity of allelic variants make these claims indefinite.

35 USC § 112, 1st paragraph

5. Claims 22, 66, 68-75 and 80 were rejected for failing to comply with the written description requirement in regards to allelic variants, fragments and polymorphic forms. This rejection is maintained. Applicant's arguments filed Dec. 2, 2004 have been fully considered but they are not persuasive because it is not clear that Applicant is in possession of all naturally occurring allelic variants of human aspartoacylase. Providing several examples, such as SEQ ID No: 10-16 and 24-27 does not constitute being in possession of everything that is claimed.

New claims 89-91 are now included in this rejection for the same reasoning as set forth in the previous Office action.

6. Claims 22, 66, 68-75 and 80 were rejected for failing to comply with the enablement requirement in regards to allelic variants, fragments and polymorphic forms. This rejection is maintained. Applicant's arguments filed Dec. 2, 2004 have been fully considered but they are not persuasive because a skilled artisan would still be required

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to perform excessive experimentation in determining the activity and viability of every single possible variant of SEQ ID No: 2.

New claims 89-91 are now included in this rejection for the same reasoning as set forth in the previous Office action.

35 USC § 102

7. Withdrawl of claim 20 overcomes the 102(b) rejection. The rejection is hereby withdrawn.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 83-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because it is unclear and undefined what stringent conditions mean.

Conclusion

10. Claims 22, 24, 66-75, 80, 83-88 and 89-91 are rejected. Claims 67, 81 and 82 are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Smm

SMM

17 December, 2004



ROBERT A. WAX
PRIMARY EXAMINER

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